In the United States Court of Federal Claims office of special masters

<u>Robert Joel Krakow</u>, Law Office of Robert J. Krakow, P.C., New York, NY for petitioners; <u>Ronalda Elnetta Kosh</u>, United States Dep't of Justice, Washington, D.C., for respondent.

<u>UNPUBLISHED DECISION DENYING COMPENSATION</u>¹

Mette Rose and Soren Rose Kjaer ("the Roses") alleged that a series of Hepatitis B vaccinations on April 13, May 16, and August 12, 2013 caused their child M.R.K. to develop uveitis. Pet., filed Apr. 13, 2016 at 3. On October 6, 2023, the Roses moved for a decision dismissing their petition.

I. <u>Procedural History</u>

The Roses filed their petition on behalf of M.R.K. on April 13, 2016. They also filed relevant medical records and affidavits. Around the same time, the Roses also filed a petition on behalf of their other child, F.R.K., for alleged uveitis caused by the Hepatitis B vaccine. Case No. 16-465V. The cases were litigated simultaneously.

The Secretary filed his Rule 4(c) Report on February 28, 2017, recommending that compensation be denied. The Secretary stated that petitioners had not provided an expert report or medical theory to support their claim that one or more Hepatitis B vaccines caused M.R.K injury. Resp't's Rep. at 10-11. The Secretary further noted that M.R.K.'s first uveitis symptoms

¹ Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

were not noted until more than a year after her third vaccine, and argued that petitioners had not established that this was an appropriate temporal relationship to injury causation. <u>Id.</u> at 11.

A status conference was held on March 17, 2017, to discuss the next steps in the case. The Roses decided to retain an expert. See Order, issued Mar. 20, 2017. The Roses were also ordered to file their VAERS report; any results of genetic testing; any records from a genetic counselor; and any additional records as they became available. Id. The parties discussed the possible existence of videotapes to help determine the onset of M.R.K.'s vision issues. Id.

After eleven extensions, the Roses filed an expert report by Dr. Frederick W. Fraunfelder on October 28, 2018. Exhibit 26. The Secretary's expert had since retired, and so additional time was necessary to retain a new expert. See Order, issued Nov. 20, 2018. After two extensions, the Secretary filed a responsive report from Dr. Jennifer E. Thorne on July 3, 2019. Exhibit A. The Roses submitted a responsive report on April 10, 2020 after eight extensions. Exhibit 51. The Secretary filed another report on August 21, 2020, and the Roses decided not to submit any additional expert reports. Exhibit C; Pet'rs' Status Rep., filed Oct. 23, 2020.

The undersigned issued an order for briefs on November 24, 2020. The Roses were ordered to file additional medical records by January 25, and their brief and prehearing materials by March 2, 2021. The Roses were granted additional time to file their brief and records, many of which were from providers in Denmark. Order, issued April 7, 2021. The Roses submitted their brief on June 30, 2021 and continued to work towards obtaining their outstanding records. They submitted records for M.R.K. as Exhibit 55, but never filed updated records for F.R.K. in their other case. The Secretary filed his brief on November 12, 2021, and petitioners replied on January 12, 2022.

On October 24, 2022, the undersigned issued an order stating that the case would proceed to oral argument to determine whether testimony was necessary. The Roses were ordered to submit an affidavit regarding genetic testing, and the Secretary was ordered to file a motion requesting genetic testing or a status report disclaiming an interest in such. The Roses, who were living in Denmark and busy caring for their children's health, were granted four extensions to file their affidavit. See Order, issued April 3, 2023. Although the Roses had not yet filed their affidavit, the Secretary filed a status report on March 27, 2023, disclaiming any interest in seeking additional genetic testing but requesting that a complete and certified set of records of any previous genetic testing be provided. The Roses stated that some genetic testing had been performed as a part of a research project, but they did not have access to the data or a report showing the results. Pet'rs' Status Rep. filed April 17, 2023.

Nine days later, the Roses asked their attorney informally by email to withdraw their petition due to the pressing circumstances of illness and hospitalization of M.R.K. Pet'rs' Status Rep., filed April 26, 2023. Counsel requested 30 days to clarify with the Roses that they wished to terminate their petitioner. A status conference was held on May 4 to discuss the next steps. The undersigned noted that the case could proceed without much direct involvement from the Roses, but that continuation would not necessarily result in an award of compensation. Counsel requested until early June to confer with the Roses about their intent to continue litigating the case. See Order, issued May 4, 2023.

Counsel made several attempts to obtained signed confirmation that the Roses wished to withdraw their petition and that they understood that withdrawal would terminate their rights in the Vaccine Injury Compensation Program. See Order, issued Sept. 19, 2023. After counsel received these documents, the Roses filed a motion for a decision dismissing the petitioner on October 6, 2023, along with a declaration confirming their intent. Exhibit 63. The Roses simultaneously moved to dismiss the case brought on behalf of F.R.K. The Roses state that they understand that dismissal will result in a judgment against them, which will terminate their rights in the Program. Pet'rs' Mot. to Dismiss at 2. The Secretary did not file a response to this motion. This matter is now ready for adjudication.

II. Analysis

To receive compensation under the National Vaccine Injury Compensation Program (hereinafter "the Program"), a petitioner must prove either 1) that the vaccinee suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations, or 2) that the vaccinee suffered an injury that was actually caused by a vaccine. See §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). Under the Act, a petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In this case, the Roses have filed some medical records, two expert reports, and briefs in support of their claim, but nonetheless, wish to have their claim dismissed and judgment entered against them. Though the Roses did not cite to a specific rule when filing this motion, the undersigned will construe this as a motion filed pursuant to 42 U.S.C. § 300aa—21(b) (regarding involuntary dismissal), given the Roses' intent that a judgment be issued against them. See Pet'rs' Mot. to Dismiss at 2.

To conform to section 12(d)(3), a decision must "include findings of fact and conclusions of law." Here, although the parties were in the process of presenting arguments, the evidence weighs against a finding that M.R.K.'s uveitis was caused by the Hepatitis B vaccinations, as the Roses have not submitted a reliable medical theory under <u>Althen</u> prong one. The Roses advance the theory that the vaccines led to the creation of immune complexes, and rely heavily on case reports/series, papers using scoring systems of unknown reliability, and articles which do not explain causation. <u>See Hazlehurst v. Sec'y of Health & Hum. Servs.</u>, 604 F.3d 1343, 1347, 1354 (Fed. Cir. 2010) (no error in special master's decision to discount opinion of doctor who relied heavily upon unreliable studies). An analysis of the other <u>Althen</u> prongs is not necessary. <u>See W.C. v. Sec'y of Health & Hum. Servs.</u>, 704 F.3d 1352, 1358 (Fed. Cir. 2013) (because a petitioner must establish all three prongs, failure to establish one prong necessarily implies a petitioner cannot establish causation under <u>Althen</u>).

Thus, the Motion for Decision is GRANTED and this case is DISMISSED WITH PREJUDICE for insufficient proof. The Clerk shall enter judgment accordingly. See Vaccine Rule 21(b).

IT IS SO ORDERED.

s/Christian J. MoranChristian J. MoranSpecial Master